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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,803	01/28/2000	ALLEN G. GOOD	AGZ-002	2681

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/493,803

Applicant(s)

GOOD, ALLEN G.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,26,37-39 and 64-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,26,37-39 and 64-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 21 November 2002 has been entered.

Drawings

2. The drawings in this application have been objected to by the Draftsperson as informal. See the PTO-948 form attached to the Office action mailed 12 February 2001. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

Claim Rejections - 35 USC § 112

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 7, 8, 26, 37-39 and 64-69 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method for directing expression of a target gene within the root of a plant comprising transforming a plant cell with a target gene in operable linkage with an abiotic stress-induced root promoter and a seed comprising said target gene in operable linkage with an abiotic stress-induced root promoter.

Applicant describes the btg26 promoter exemplified by SEQ ID NO: 1 that has root-preferred function and is induced by osmotic-stress and a method of expressing a target gene in a root under osmotic stress conditions (see Example 5 on pages 38-42 of the specification).

Applicant does not describe other abiotic stress-induced root promoters or other btg26 root promoters and thus does not describe a method using other abiotic stress-induced root promoters.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes,

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even when accompanied by a method of obtaining the claimed sequence. In the instant case, Applicant describes only one species of the genus required to practice the claimed method and make the claimed seed and does not describe what special features are shared by all abiotic stress-induced root promoters as broadly claimed.

5. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method for directing root-specific expression of a target gene in a plant with the btg-26 promoter of SEQ ID NO: 1 wherein said promoter is osmotically regulated and a seed comprising said promoter, does not reasonably provide enablement for a method for directing root-specific expression of a target gene in a plant with any root-specific promoter and wherein said root-specific promoter is environmentally or developmentally regulated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2002. Applicant's arguments filed 21 November 2002 have been fully considered but they are not persuasive.

Applicant argues that amendments to the claims to indicate that the promoter is a root promoter more specifically define the subject matter (page 3 of the Remarks/Arguments).

This argument is not found to be persuasive for the reasons given in the previous Office action mailed 22 October 2001. At claim 26, the list of abiotic stress parameters

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exemplifies the Examiner's arguments that undue trial and error experimentation would have been required by one of skill in the art at the time of Applicant's invention to identify and isolate a myriad of abiotic stress-induced root promoters to practice the claimed method and produce the claimed seed within the full breadth of the claims.

Claim Rejections - 35 USC § 102

6. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under 35 U.S.C. §102(e) as being anticipated by Good *et al* (U.S. Patent 6,084,153). This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2001. Applicant's arguments filed 21 November 2002 have been fully considered but they are not persuasive.

Applicant argues that the subject matter of the instant claims pertain to a method of expressing a target gene in a plant using an abiotic, stress-induced root-specific promoter and that there is no teaching within Good *et al* of root-specific expression of a target gene (see page 3 of the Remarks/Argument). This argument is not found to be persuasive because the fact that Good *et al* in the '153 patent does not disclose root-specific promoter activity does not obviate this rejection if the promoter of Good *et al* inherently has such a promoter activity.

See *ex parte* Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition

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but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating).

Double Patenting

7. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,084,153. This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2001. Applicant states that a terminal disclaimer will be filed upon an indication from the Examiner that the application is otherwise in condition for allowance (page 4 of the Remarks/Arguments).

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Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
23 January 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600